



IFW

CASE HA0801 NP

CERTIFICATE OF MAILING

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Kathleen Bodine
Type or print name

Kathleen Bodine
Signature

May 27, 2004
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

RIDKER ET AL.

APPLICATION NO: 10/767,758

FILED: JANUARY 29, 2004

FOR: METHOD FOR PREVENTING RECURRENT VENOUS
THROMBOEMBOLISM USING LONG-TERM LOW-INTENSITY
WARFARIN

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants believe this paper is being filed before the mailing date of a first Office Action on the merits, and so under 37 C.F.R. §1.97(b)(3) no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-3880.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

Copies of these references are enclosed herewith.

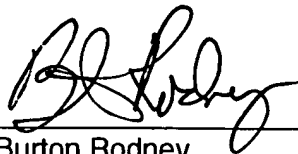


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PATENT TRADEMARK OFFICE

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Burton Rodney', is written over a horizontal line.

Burton Rodney
Attorney for Applicants
Reg. No. 22,076

Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000
(609) 252-4336

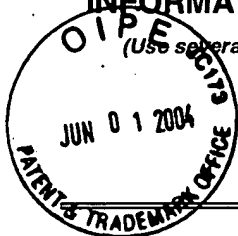
Date: May 27, 2004

FORM PTO-1449
(REV. 7-85)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
HA0801 NP
APPLICATION NO.
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APPLICANT
RIDKER ET AL.
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Group

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AM						<input type="checkbox"/>	<input type="checkbox"/>
	AN						<input type="checkbox"/>	<input type="checkbox"/>
	AO						<input type="checkbox"/>	<input type="checkbox"/>
	AP						<input type="checkbox"/>	<input type="checkbox"/>
	AQ						<input type="checkbox"/>	<input type="checkbox"/>

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

	AR	Agnelli, G. et al., "Three Months Versus One Year of Oral Anticoagulant Therapy for Idiopathic Deep Venous Thrombosis", N. Engl. J. Med., Vol. 345, No. 3, pp. 165-169 (2001)
	AS	Bern, M.M. et al., "Very Low Doses of Warfarin Can Prevent Thrombosis in Central Venous Catheters: A Randomized Prospective Trial", Annals of Internal Medicine, Vol. 112, No. 6, pp. 423-428 (1990)
	AT	Bertina, R.M. et al., "Mutation in blood coagulation factor V associated with resistance to activated protein C", Nature, Vol. 369, pp. 64-67 (1994)

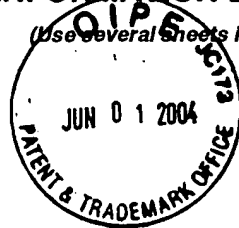
EXAMINER**DATE CONSIDERED**

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	2AA	Beyth, R.J. et al., "Prospective Evaluation of an Index for Predicting the Risk of Major Bleeding in Outpatients Treated with Warfarin", Am. J. Med., Vol. 105, pp. 91-99 (1998)
	2AB	De Stefano, V. et al., "The Risk of Recurrent Deep Venous Thrombosis Among Heterozygous Carriers of Both Factor V Leiden and the G20210A Prothrombin Mutation", N. Engl. J. Med., Vol. 341, No. 11, pp. 801-806 (1999)
	2AC	Eichinger, S. et al., "The Risk of Recurrent Venous Thromboembolism in Patients with and without Factor V Leiden", Thrombosis and Haemostasis, Vol. 77, No. 4, pp. 624-628 (1997)
	2AD	Eriksson, H. et al., "Extended Secondary Prevention with Oral Direct Thrombin Inhibitor Ximelagatran for 18 Months after 6 Months of Anticoagulation in Patients with Venous Thrombo- embolism: A Randomized Placebo-Controlled Trial", American Society of Hematology, Abstract #297, page 81a, December, 2002.
	2AE	Eriksson, H. et al., "The Oral Direct Thrombin Inhibitor Ximelagatran, and Its Subcutaneous (sc) Form Melagatran, Compared With Enoxaparin for Prophylaxis of Venous Thromboembolism (VTE) in Total Hip or Total Knee Replacement (THR or TKR): The EXPRESS Study", American Society of Hematology, Abstract #299, page 82a, December, 2002
	2AF	Fihn, S.D. et al., "The Risk for and Severity of Bleeding Complications in Elderly Patients Treated with Warfarin", Annals of Internal Medicine, Vol. 124, No. 11, pp. 970-979 (1996)
	2AG	Hillarp, A. et al., "The 20210 A Allele of the Prothrombin Gene Is a Common Risk Factor among Swedish Outpatients with Verified Deep Venous Thrombosis", Thromb. Haemost., Vol. 78, pp. 990-992 (1997)
	2AH	Hirsh, J., "The Optimal Duration of Anticoagulant Therapy for Venous Thrombosis", The New England Journal of Medicine, Vol. 332, No. 25, pp. 1710-1711 (1995)
	2AI	Kearon, C. et al., "A Comparison of Three Months of Anticoagulation with Extended Anticoagulation for a First Episode of Idiopathic Venous Thromboembolism", The New England Journal of Medicine, Vol. 340, No. 12, pp. 901-907 (1999)
	2AJ	Lan, K.K.G. et al., "Discrete sequential boundaries for clinical trials", Biometrika, Vol. 70, No. 3, pp. 659-663 (1983)
	2AK	Levine, M. et al., "Double-blind randomised trial of very-low-dose warfarin for prevention of thromboembolism in stage IV breast cancer", The Lancet, Vol. 343, pp. 886-889 (1994)
	2AL	Lindmarker, P. et al., "The Risk of Recurrent Venous Thromboembolism in Carriers and Non-carriers of the G1691A Allele in the Coagulation Factor V Gene and the G20210A Allele in the Prothrombin Gene", Thromb. Haemost., Vol. 81, pp. 684-689 (1999)
	2AM	McMahan, D.A. et al., "Risk of Major Hemorrhage for Outpatients Treated with Warfarin", J. Gen. Intern. Med., Vol. 13, pp. 311-316 (1998)
	2AN	Miles, J.S. et al., "G20210A Mutation in the Prothrombin Gene and the Risk of Recurrent Venous Thromboembolism", Journal of the American College of Cardiology, Vol. 37, No. 1, pp. 215-218 (2001)

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3AA	Millenson, M.M. et al., "Monitoring 'Mini-Intensity' Anticoagulation With Warfarin: Comparison of the Prothrombin Time Using a Sensitive Thromboplastin With Prothrombin Fragment F ₁₊₂ Levels", Blood, Vol. 79, No. 8, pp. 2034-2038 (1992)
3AB	Poller, L. et al., "Reduction of factor VII coagulant activity (VIIC), a risk factor for ischaemic heart disease, by fixed dose warfarin: a double blind crossover study", Br. Heart J., Vol. 63, pp. 231-233 (1990)
3AC	Poort, S.R. et al., "A Common Genetic Variation in the 3'-Untranslated Region of the Prothrombin Gene Is Associated With Elevated Plasma Prothrombin Levels and an Increase in Venous Thrombosis", Blood, Vol. 88, No. 10, pp. 3698-3703 (1996)
3AD	Prandoni, P. et al., "The Long-Term Clinical Course of Acute Deep Venous Thrombosis", Annals of Internal Medicine, Vol. 125, No. 1, pp. 1-7 (1996)
3AE	Price, D.T. et al., "Factor V Leiden Mutation and the Risks for Thromboembolic Disease: A Clinical Perspective", Ann. Intern. Med., Vol. 127, No. 10, pp. 895-903 (1997)
3AF	Ridker, P.M., "Long-term, low-dose warfarin among venous thrombosis patients with and without factor V Leiden mutation: rationale and design for the Prevention of Recurrent Venous Thromboembolism", Vascular Medicine, Vol. 3, pp. 67-73 (1998)
3AG	Ridker, P.M. et al., "Factor V Leiden and Risks of Recurrent Idiopathic Venous Thromboembolism", Circulation, Vol. 92, No. 10, pp. 2800-2802 (1995)
3AH	Ridker, P.M. et al., "Mutation in the Gene Coding for Coagulation Factor V and the Risk of Myocardial Infarction, Stroke, and Venous Thrombosis in Apparently Healthy Men", The New England Journal of Medicine, Vol. 332, No. 14, pp. 912-917 (1995)
3AI	Schulman, S. et al., "A Comparison of Six Weeks with Six Months of Oral Anticoagulant Therapy After a First Episode of Venous Thromboembolism", The New England Journal of Medicine, Vol. 332, No. 25, pp. 1661-1665 (1995)
3AJ	Schulman, S. et al., "The Duration of Oral Anticoagulant Therapy After a Second Episode of Venous Thromboembolism", Vol. 336, No. 6, pp. 393-398 (1997)
AK	Simioni, P. et al., "The Risk of Recurrent Venous Thromboembolism in Patients with an Arg ⁵⁰⁶ →Gln Mutation in the Gene for Factor V (Factor V Leiden)", N. Engl. J. Med., Vol. 336, No. 6, pp. 399-403 (1997)
AL	Svensson, P.J. et al., "Resistance to Activated Protein C as a Basis for Venous Thrombosis", The New England Journal of Medicine, Vol. 330, No. 8, pp. 517-522 (1994)
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AN	

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